REMARKS

The applicants are amending the application to include the status of the parent application (now abandoned) as requested by the Examiner.

The 35 U.S.C. 112 First Paragraph Rejection is Overcome

Claims 1-18 were rejected under 35 U.S.C. 112, first paragraph. The Examiner contends that the amendment to claims 1 and 16 added new matter to the application. Claims 1 and 16 have been rewritten as new claims 23 and 38, respectively, to overcome this rejection. Both claims 23 and 38 recite the limitation that the reaction chamber, transition region, and separation region are formed in and enclosed by the body.

The 35 U.S.C. 102 Rejection based on Wilding is Overcome

Claims 1, 8, and 13-15 were rejected under 35 U.S.C. 102 as being anticipated by Wilding (U.S. Patent 5,587,128). The Examiner contends that Fig. 12 of Wilding shows a device as claimed by the applicants in claim 1. Claim 1 has been rewritten as new claim 23 so that this rejection is now construed to apply to claim 23. There are significant differences between the device taught by Wilding and the device recited by the applicants in claim 23.

First, the device taught by Wilding lacks a unitary body enclosing a reaction chamber, separation region, and transition region as recited in claim 23. Specifically, Wilding teaches that the device is constructed by fabricating flow channels and one or more reaction chambers into the surface of a substrate (e.g., a silicon substrate) and then adhering or clamping a cover (e.g., a glass substrate) over the surface (column 7, lines 28-32). This multi-substrate device taught by Wilding is contrary to the

"unitary body" defined by the applicants in the specification and recited in claim 23.

Second, the applicants' claim 23 includes the limitation that the portion of the unitary body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially thermally isolates the reaction chamber from the separation region. Wilding fails to teach this limitation. Fig. 12 of Wilding shows a multi-substrate body constructed of a first substrate bonded or clamped to a second substrate. Nowhere does Wilding state that the portion of his device defining a transition region should have lower thermal conduction than the portion of the device defining the reaction chamber, but this feature is explicitly recited by the applicants in claim 23.

It is well established by patent case law that for a reference to support a rejection under 35 U.S.C. 102, that reference must teach each feature recited in the claims so rejected. It has been clearly shown that Wilding fails to teach each feature recited in claim 23. Thus, this ground of rejection is improper and should be withdrawn.

Moreover, the applicants submit that the device of claim 23 is unobvious and therefore patentable in view of Wilding. Wilding fails to suggest constructing a device having a transition region that thermally isolates the reaction chamber from a separation region as recited by the applicants in claim 23. Wilding also teaches away from the concept of a unitary body as recited by the applicants in claim 23. Specifically, Wilding suggests construction of the device using the following procedure. "Flow channels or chambers of varying widths and depths can be fabricated … in a substrate such as silicon. The substrate

containing a fabricated mesoscale flow channel and reaction chamber may be covered and sealed with a glass cover clamped, anodically bonded or otherwise adhered to the substrate. Other clear or opaque cover materials may be used. Alternatively, two substrates can be sandwiched, or a substrate can be sandwiched between two glass covers" (column 14, lines 50-59).

Clearly, Wilding teaches multi-substrate construction of his device which is contrary to a device having a unitary body as recited by the applicants in claim 23. The applicants therefore submit that claim 23 is unobvious in view of Wilding. The dependent claims 24-37 incorporate all of the subject matter of independent claim 23 and add further limitations, which makes them a fortiori patentable over Wilding. Therefore, the applicants submit that all claims 23-37 are patentable over Wilding.

The 35 U.S.C. 102 Rejection of Claim 23 based on Jerman is Overcome

Claims 1-4, 7, 8, and 10-22 were rejected under 35 U.S.C. 102 as being anticipated by Jerman (U.S. Patent 5,824,204). The Examiner contends that Fig. 3A of Jerman anticipates claim 1. Claim 1 has been rewritten as new claim 23 so that this rejection is now construed to apply to claim 23. There are significant differences between the device taught by Jerman and the device recited by the applicants in claim 23.

First, the device taught by Jerman lacks a unitary body enclosing a reaction chamber, separation region, and transition region as recited in claim 23. Specifically, Jerman teaches that the device is constructed by depositing silicon nitride on a sacrificial silicon wafer and bonding the silicon wafer to an insulating substrate (column 2, lines 39-49). This multi-substrate device

taught by Jerman is contrary to the unitary body defined by the applicants in the specification and recited in claim 23.

Second, the applicants' claim 23 recites that the device includes at least one flow restrictor in the transition region for controlling the flow of fluid between the reaction chamber and the separation region. Jerman fails to describe this feature. Third, the applicants' claim 23 states that the portion of the unitary body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially thermally isolates the reaction chamber from the separation region. Jerman fails to describe this feature as well. It is well established by patent case law that for a reference to support a rejection under 35 U.S.C. 102, that reference must teach each feature recited in the claims so rejected. It has been clearly shown that Jerman fails to teach each feature recited in claim 23. Thus, this ground of rejection is improper and should be withdrawn.

Moreover, the applicants submit that the device of claim 23 is unobvious and therefore patentable in view of Jerman. Jerman lacks any suggestion that the device of Fig. 3A should be modified in a manner required to meet claim 23. In particular, Jerman does not suggest a flow restrictor in a transition region as recited by the applicants in claim 23. In addition, Jerman teaches away from the concept of a unitary body as recited by the applicants in claim 23. Specifically, Jerman teaches in great detail construction of the device using silicon nitride, a sacrificial silicon wafer, and an underlying glass substrate. Jerman's teachings are contrary to a device having a unitary body as defined by the applicants' in the specification and recited in claim 23.

The applicants further submit that the novel physical features of claim 23 produce new and superior results and hence are unobvious and patentable over Jerman. These new and superior results are the ability of the applicants' device to heat a sample in a reaction chamber and to separate components of the sample using a separation region in the same device without the heat from the reaction chamber degrading performance in the separation region. These superior results are achieved in the applicants' device because the portion of the unitary body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially thermally isolates the reaction chamber from the separation region, as explicitly recited in claim 23.

In contrast, the device shown in Figs. 3A-3B of Jerman fails to thermally isolate the reaction chamber 24 from the separation column 70. In Jerman's device, both the reaction chamber and the transition region are defined by the glass substrate 10 and the silicon nitride structures 20. Jerman does not teach that the separation column 70 should be thermally isolated from the heat of the reaction chamber 24, nor does he make any provisions for ensuring this thermal isolation. Thus, when the heater trace 68 is activated to heat silicon structures 58 and 60, the entire glass substrate 10 is heated as well, including the portion of the substrate 10 that defines the separation column 70. Thus, there is significant thermal conduction into the separation column 70 through the glass substrate 10, causing a temperature gradient within the separation column 70. A temperature gradient in the separation column 70 will significantly degrade the performance of the device. The applicants' note that the layer of polyamide 66 applied to the glass substrate 10 for insulative purposes serves to increase the amount of heat retained in the

glass substrate 10 and thus adds to the creation of the thermal gradient in the separation column 70.

The applicants have recognized that for the effective separation of sample components, it is important to maintain a substantially uniform temperature in the separation region and that a uniform temperature may be achieved by thermally isolating the reaction chamber from the separation region. Because the applicants' invention, as recited in claim 23, solves a problem unrecognized by Jerman, the applicants submit that their invention, as recited in claim 23, is unobvious and therefore patentable in view of Jerman.

The dependent claims 24-37 incorporate all of the subject matter of independent claim 23 and add further limitations, which makes them a fortiori patentable over Jerman. Therefore, the applicants submit that all claims 23-37 are patentable over Jerman.

The 35 U.S.C. 102 Rejection of Claim 16 based on Jerman is Overcome

Claims 1-4, 7, 8, and 10-22 were rejected under 35 U.S.C. 102 as being anticipated by Jerman (U.S. Patent 5,824,204). The Examiner contends that Jerman anticipates claim 16. Claim 16 has been rewritten as claim 38 so that this rejection is now construed to apply to claim 38.

There are significant differences between the method for producing a device taught by Jerman and the method for producing a device claimed by the applicants in claim 38. In particular, the applicants' claim 38 includes the step of molding a one-piece polymeric body having a reaction chamber, separation region, and transition region. In contrast, Jerman teaches construction of his device by etching the desired groove, chamber, and through-hole

features in the surface of a sacrificial silicon wafer using conventional micromachining etching techniques, depositing a layer of low stress silicon nitride material onto the wafer surface so that the layer conformally coats the etched features, and photolithographically patterning the layer to define various silicon nitride features. The silicon wafer is then bonded to an insulating substrate and all (or selected portions) of the silicon wafer are then removed (sacrificed) using etchants. A silicon nitride "shell" then remains bonded to the glass substrate, and the shell substantially duplicates the etched geometries in the sacrificial silicon wafer. (column 2, lines 35-55).

Jerman makes no mention of molding a one-piece polymeric body, but this step is explicitly recited by the applicants in claim 38. It is well established by patent case law that for a reference to support a rejection under 35 U.S.C. 102, that reference must teach each feature or method step recited in the claims so rejected. It has been clearly shown that Jerman fails to teach each method step recited in claim 38. Thus, this ground of rejection is improper and should be withdrawn.

Moreover, the applicants submit that the method of claim 38 is unobvious and therefore patentable in view of Jerman. The method recited in the applicants' claim 38 is contrary to the multi-substrate construction methods taught by Jerman, and Jerman lacks any suggestion that his device should be constructed by molding a one-piece polymeric body. The dependent claims 39-40 incorporate all of the subject matter of independent claim 38 and add further limitations, which makes them a fortiori patentable over Jerman. Therefore, the applicants submit that all claims 38-40 are patentable over Jerman.

The 35 U.S.C. 102 Rejection of Claim 41 based on Jerman is Overcome

Claims 19-22 were rejected under 35 U.S.C. 102 as being anticipated by Jerman (U.S. Patent 5,824,204). The Examiner contends that Fig. 3A of Jerman anticipates claim 19. Claim 19 has been rewritten as claim 41 so that this rejection is now construed to apply to claim 41. There are significant differences between the device taught by Jerman and the device claimed by the applicants in claim 41.

First, claim 41 explicitly recites that the applicants' device includes at least one flow restrictor in the transition region for controlling the flow of fluid between the reaction chamber and the separation region. This feature of the applicants' invention is not described in the Jerman patent. Second, the applicants' claim 41 states that the portion of the unitary body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially thermally isolates the reaction chamber from the separation region. Jerman fails to describe this feature as well. It is well established by patent case law that for a reference to support a rejection under 35 U.S.C. 102, that reference must teach each feature recited in the claims so rejected. Jerman fails to teach each feature recited in claim 41. Thus, this ground of rejection is improper and should be withdrawn.

The applicants further submit that the novel physical features of claim 41 produce new and superior results and hence are unobvious and patentable over Jerman. These new and superior results are the ability of the applicants' device to heat a sample in a reaction chamber and to separate components of the sample using a separation region in the same device without the heat from the

reaction chamber degrading performance in the separation region. These superior results are achieved in the applicants' device because the portion of the unitary body defining the transition region has lower thermal conduction than the portion of the body defining the reaction chamber so that the transition region substantially thermally isolates the reaction chamber from the separation region, as explicitly recited in claim 41.

In contrast, the device shown in Figs. 3A-3B of Jerman fails to thermally isolate the reaction chamber 24 from the separation column 70. In Jerman's device, both the reaction chamber and the transition region are defined by the glass substrate 10 and by silicon nitride structures 20. Jerman does not teach that the separation column 70 should be thermally isolated from the heat of the reaction chamber 24, nor does he make provisions for ensuring this thermal isolation. Thus, when the heater trace 68 is activated to heat silicon structures 58 and 60, the entire glass substrate 10 is heated as well, including the portion of the substrate 10 that defines the separation column 70. Thus, there is significant thermal conduction into the separation column 70 through the glass substrate 10, causing a temperature gradient within the separation column 70. A temperature gradient in the separation column 70 will significantly degrade the performance of the device. The applicants' note that the layer of polyamide 66 applied to the glass substrate 10 for insulative purposes serves to increase the amount of heat retained in the glass substrate 10 and thus adds to the severity of the thermal gradient in the separation column 70.

The applicants have recognized that for the effective separation of sample components, it is important to maintain a substantially uniform temperature in the separation region and that a uniform temperature may be achieved by thermally isolating the reaction

chamber from the separation region. Because the applicants' invention, as recited in claim 41, solves a problem unrecognized by Jerman and provides for superior results, the applicants submit that their invention, as recited in claim 41, is unobvious and therefore patentable in view of Jerman.

The dependent claims 42-44 incorporate all of the subject matter of independent claim 41 and add further limitations, which makes them a fortiori and independently patentable over Jerman. Claim 42 additionally recites a filter positioned in the transition region such that when the voltage is applied between the first and second electrodes, the components in the sample are transported from the reaction chamber to the transition region and collected on the filter, and such that when the subsequent voltage is applied between the second and third electrodes, the components collected on the filter are transported into the separation region. Jerman does not teach a transition region containing a filter, nor does the word "filter" even appear in the Jerman patent. Thus, the applicants submit that claim 42 is novel and unobvious in view of Jerman.

Claim 43 additionally recites that the device includes at least one side channel communicating with the transition region, and at least one flow controller in the side channel for controlling the flow of fluids through the side channel. Jerman does not teach a side channel containing a flow controller. Thus, the applicants submit that claim 43 is novel and unobvious in view of Jerman.

Claim 44 further recites that the side channel connects to the transition region upstream of the flow restrictor, and wherein the transition region further includes a collection area for mixing the sample with one or more reagents. Jerman does not teach a transition region that includes a collection area for

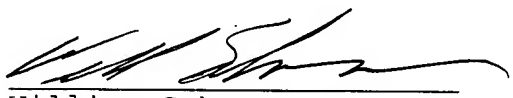
mixing the sample with reagents. Thus, the applicants submit that claim 44 is novel and unobvious in view of Jerman.

It is requested that if the Examiner once again rejects any one of claims 41-44 under 35 U.S.C. 102 in view of Jerman, the Examiner present a convincing line of reasoning explaining how Jerman anticipates each feature in claims 41-44. The applicants submit that claims 41-44 contain features that are novel and unobvious in view of Jerman.

Conclusion

For all of the above reasons, the applicants submit that the pending claims are now in proper form and that the claims define patentably over the prior art. The applicants therefore submit that this application is in condition for allowance, which action they respectfully solicit.

Respectfully submitted,



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